IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PIRAMAL HEALTHCARE UK LIMITED, Plaintiff, v. SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Defendants.	Case No. _____

COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT

Plaintiff Piramal Healthcare UK Limited ("Piramal"), for its complaint against Defendants Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This case arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

2. Piramal brings this case pursuant to 21 U.S.C. § 355(j)(5)(C)(i), entitled "Declaratory Judgement Absent Infringement Action," which provides that the holder of an Abbreviated New Drug Application ("ANDA") may file an action for declaratory judgment of non-infringement with respect to a patent that is the subject of a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) (i.e., a "Paragraph IV certification") in the event that the patent owner does not file suit for infringement of the patent against the ANDA holder. *See Dey Pharma, LP v. Sunovion Pharms Inc.*, 677 F.3d 1158 (Fed. Cir. 2012).

THE PARTIES

3. Piramal is a corporation organized and existing under the laws of the United Kingdom, having a principal place of business at Whalton Road, Morpeth, Northumberland, NE61 3YA, United Kingdom.

4. On information and belief, Sumitomo is a company organized and existing under the laws of Japan, with a principal place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

5. On information and belief, Sunovion is a corporation organized and existing under the laws of Delaware, with a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

6. On information and belief, Sunovion is a wholly-owned subsidiary of Sumitomo.

7. On information and belief, Sumitomo and Sunovion are in the business of developing, manufacturing, distributing, and selling pharmaceuticals throughout the United States, including in the District of New Jersey.

JURISDICTION AND VENUE

8. The Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

9. The Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, directly or through their subsidiaries, agents, and/or affiliates, Defendants regularly and continuously transact business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Defendants derive substantial revenue from the sale

of pharmaceutical products in New Jersey and have availed themselves of the privilege of conducting business within New Jersey.

10. Further, the Court has personal jurisdiction over Defendants by virtue of their having filed Civil Action No. 2:18-cv-13478-SRC-CLW in the District of New Jersey, alleging infringement of U.S. Patent No. 9,815,827 by Piramal based on Piramal's filing of ANDA No. 212091 for lurasidone hydrochloride tablets, the same ANDA that is involved in this action.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

ACTS GIVING RISE TO THIS ACTION

12. On May 20, 2014, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,729,085 B2 ("the '085 patent"), entitled "Pharmaceutical Composition." On information and belief, Sumitomo is the owner or assignee of the '085 patent.

13. On information and belief, Sunovion is the holder of New Drug Application ("NDA") No. 200603 for lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, 120 mg), marketed and sold by Sunovion in the United States under the brand name Latuda®.

14. According to records of the U.S. Food and Drug Administration ("FDA"), Sunovion's NDA No. 200603 for Latuda® was approved on October 28, 2010.

15. Sunovion submitted the '085 patent for listing in the electronic version of the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Latuda®.

16. By maintaining the listing of the '085 patent in the Orange Book, Sunovion represents to the FDA and the public that the '085 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1).

17. By letter dated July 19, 2018 ("Piramal's Notice Letter"), Piramal notified Sumitomo and Sunovion that it had filed ANDA No. 212091 for lurasidone hydrochloride tablets ("Piramal's ANDA Products") and included a Paragraph IV certification that the '085 patent is invalid, unenforceable, and/or will not be infringed by Piramal's ANDA Products.

18. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Piramal's Notice Letter included a detailed statement of the factual and legal basis for the certification that the '085 patent is invalid, unenforceable, and/or will not be infringed by Piramal's ANDA Products.

19. Piramal's Notice Letter also included an Offer of Confidential Access to its ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

20. On August 31, 2018, Defendants filed suit against Piramal, alleging that Piramal's ANDA No. 212091 infringes two other patents, U.S. Patent Nos. 9,815,827 and 8,883,794, but not the '085 patent. *Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Piramal Healthcare UK Limited*, No. 2:18-cv-13478-SRC-CLW (D.N.J.).

21. On October 3, 2018, Piramal produced a complete copy of its ANDA No. 212091 to Defendants.

22. On October 24, 2018, Defendants filed an Amended Complaint against Piramal, alleging infringement of only the '827 patent. *Id.*, D.I. 16.

23. On March 25, 2019, the FDA granted tentative approval to Piramal's ANDA No. 212091.

24. On information and belief, several other companies have filed an ANDA for lurasidone hydrochloride tablets that included a Paragraph IV certification to the '085 patent. *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Emcure Pharms. Ltd. et al.*, No. 2:18-cv-02065-SRC-CLW (D.N.J.) ("Consolidated Action").

25. On information and belief, Sumitomo and Sunovion did not assert the '085 patent against any of the ANDA applicants named as defendants in the Consolidated Action. Further, Sumitomo and Sunovion reached settlement agreements with all of the defendants in the Consolidated Action before the Court reached a final decision on the merits.

26. On information and belief, at least one of the defendants in the Consolidated Action filed an ANDA with a Paragraph IV certification to the '085 patent on October 28, 2014, which, due to New Chemical Entity exclusivity in connection with Latuda®, was the first day on which FDA would accept an ANDA with a Paragraph IV certification for a generic version of Latuda®.

27. On information and belief, by filing an ANDA with a Paragraph IV certification to the '085 patent on October 28, 2014, at least one of the defendants in the Consolidated Action is a "first applicant" under 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) and is therefore entitled to 180-day exclusivity in connection with its lurasidone hydrochloride ANDA. Accordingly, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I), FDA cannot grant final approval of Piramal's ANDA No. 212091 until such 180-day exclusivity expires or is forfeited.

28. Piramal intends to market its ANDA Products immediately upon receiving final approval of its ANDA No. 212091.

29. But for Defendants' listing of the '085 patent in the Orange Book, final FDA approval of Piramal's ANDA would not be blocked by 180-day exclusivity.

30. A first applicant may forfeit its 180-day exclusivity if it fails to market its ANDA product within 75 days of a "final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent [qualifying the first applicant for the 180-day exclusivity period] is invalid or not infringed." 21 U.S.C. §

355(j)(5)(D)(i)(I). *See also Granisetron FDA Letter Decision*, FDA Docket No. 2007N-0389 (2008). Accordingly, by obtaining a final decision of non-infringement of the '085 patent, Piramal may trigger a forfeiture of the 180-day exclusivity and thereby remove the barrier to final FDA approval of its ANDA.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '085 Patent)

31. Piramal restates and realleges each of the foregoing paragraphs 1-30 as if fully set forth herein.

32. The '085 patent claims are narrowly limited to pharmaceutical formulations comprising lurasidone hydrochloride and specific excipients in specific amounts.

33. Piramal's ANDA Products do not meet each and every limitation of the claims of the '085 patent, either literally or under the doctrine of equivalents, and therefore they do not infringe the claims of the '085 patent.

34. Due to prosecution history estoppel arising from arguments and amendments made during prosecution of the '085 patent, Defendants are precluded from asserting infringement of the '085 patent under the doctrine of equivalents against Piramal.

35. Defendants caused the '085 patent to be listed in the Orange Book, thereby excluding Piramal from selling their non-infringing product and resulting in injury to Piramal.

36. Piramal's injury is fairly traceable to Defendants and redressable by a declaratory judgment that Piramal's ANDA Products do not infringe the '085 patent.

37. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Piramal and Defendants regarding infringement of the '085 patent.

38. Piramal is entitled to a judicial declaration that the filing of Piramal's ANDA No. 212091 has not infringed any claim of the '085 patent, and that the manufacture, use, sale, offer

for sale, or importation of Piramal's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly or indirectly, any claim of the '085 patent, either literally or under the doctrine of equivalents.

STATEMENT OF RELATED CASES

On August 31, 2018, Defendants filed suit against Piramal in the United States District Court for the District of New Jersey, alleging that Piramal's ANDA No. 212091 infringes U.S. Patent Nos. 9,815,827 and 8,883,794. *Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Piramal Healthcare UK Limited*, Case No. 2:18-cv-13478-SRC-CLW. Defendants filed an Amended Complaint on October 24, 2018, asserting only U.S. Patent No. 9,815,827.

PRAYER FOR RELIEF

WHEREFORE, Piramal respectfully prays for judgment in its favor and against Defendants:

(a) Declaring that the filing of Piramal's ANDA No. 212091 has not infringed any claim of the '085 patent;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of Piramal's ANDA Products have not infringed, do not infringe, and would not infringe any claim of the '085 patent, either directly or indirectly and either literally or under the doctrine of equivalents;

(c) Awarding Piramal its reasonable attorney's fees, expenses, and costs pursuant to 35 U.S.C. § 285; and

(d) Awarding Piramal such other relief as the Court may deem just and proper.

Dated: June 26, 2019

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